

REMARKS

Election/Restrictions

Applicants acknowledge that the restriction requirement is made final and that claims 114, 115, 117-119 and 121 are under examination. Claims 122-127 were cancelled without prejudice or disclaimer. Applicants respectfully request that claim 116 be rejoined with Group I because a bacteriophage is a species of virus. Additionally, Applicants note that U.S.S.N. 10/561,829 originated in the United States and was filed in with United States Receiving Office. Therefore, 35 U.S.C. § 372(b)(2) does not apply to this application.

Objections to the Specification

Applicants amended the specification to replace Table 1 and to remove the hypertext link. Applicants also replaced the Abstract. In view of these amendments, the objection is moot. No new matter was introduced.

Amendment to the Claims

Claim 114 was amended to clarify that the claim is directed to a recombinant viral vector having viral capsid proteins that include a protein transduction domain and an organelle localization signal. Basis for the amendment is found in the specification as originally filed for example on page 18, lines 8-10, and page 19, lines 11-14. No new matter is introduced. Claim 114 falls within Group I because it incorporates the elements of claim 115 which was in Group I.

Rejection under 35 U.S.C. § 112, second paragraph

Claims 114, 115, 117-119 and 121 were rejected under 35 U.S.C. § 112, second paragraph as being indefinite. Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claim 114 was amended to delete the element relating to linking a polynucleotide to a polypeptide. In view of this amendment, the rejection is moot.

Rejections under 35 U.S.C. § 102(b)

Claims 114, 117, 119, and 121 were rejected under 35 U.S.C. § 102(b) as anticipated by Del Gaizo et al. (Mole. Ther 2003, 7:720-30). Applicants respectfully traverse the rejection to the extent it is applied to the claims as amended.

Applicants note that claim 115 was not rejected under 35 U.S.C. § 102(b). Claim 114 was amended to incorporate the elements of claim 115, and claim 115 was canceled. Claim 114 was further amended to clarify that the capsid protein contains contain a transduction domain and an organelle localization signal. Del Gaizo et al. does not disclose a recombinant viral vector having-viral capsid proteins encasing a polynucleotide, wherein the viral capsid proteins have an organelle localization signal operably linked to a protein transduction domain. Therefore, Del Gaizo et al. does not anticipate claims 114, 117, 119 and 121.

Rejection Under 35 U.S.C. § 103

Claims 114, 117, 119, and 121 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang et al. (FEBS 2002:532-36-44) in view of Baltzan et al. (PNAS 1995:9219:-23). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claims 115 and 118 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang et al. (FEBS 2002:532-36-44) in view of Baltzan et al. (PNAS 1995:9219:-23) and further in view of Robbins et al. (Pharmacol Ther, 80:35-47 (1998)). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Claims 119 was rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang et al. (FEBS 2002:532-36-44) in view of Baltzan et al. (PNAS 1995:9219:-23) and further in view of Hashimoto et al. (Biochem Biophys Res Comm 283:460-468 (2001)) and Maximov (Med Hypothesis 59:670-673 (2002)). Applicants respectfully traverse this rejection to the extent that it is applied to the claims as amended.

Legal Standard

The starting point for an obviousness determination must be the Supreme Court's decision in *KSR v. Teleflex*, 550 U.S. 398 (2007), which refocuses the determination of whether a claimed invention is obvious back to the process the Court had defined in *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17-18 (1966). There, the Court had held that the obviousness determination should address four factors, all of which must be considered, though not in any prescribed order: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed invention and the prior art; and (4) any secondary considerations suggesting nonobviousness, such as commercial success, failure of others, and long felt but unmet need. *Id.* The Court cautioned that the fact finder should be careful about reading the teachings of the invention at issue into the prior art, to avoid applying inappropriate hindsight, *ex post* reasoning. *Id.* at 36.

Even where the prior art suggests or motivates an inventor to develop the composition or process at issue, the Federal Circuit continues to recognize that there is a critical question under 35 U.S.C. § 103 as to whether the combined teachings of the prior art "would have given rise to a reasonable expectation of success" in achieving what is claimed. *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007), cert. denied, (U.S. 2008).

The Examiner's attention is directed to the Court of Appeals for the Federal Circuit decision, *In re Kubin*, 561 F.3d 1351 (Fed. Cir. 2009). The following quotes from this decision clarify when "obvious to try" is "obviousness", and when it is not.

"The Supreme Court's admonition against a formalistic approach to obviousness in this context actually resurrects this court's own wisdom in *In re O'Farrell*, which predates the *Deuel* decision by some seven years. This court in *O'Farrell* cautioned that "obvious to try" is an incantation whose meaning is often misunderstood:

' It is true that this court and its predecessors have repeatedly emphasized that "obvious to try" is not the standard under § 103. However, the meaning of this maxim is sometimes lost. Any invention that would in fact have been obvious under § 103 would also have been, in a sense, obvious to try. The question is: when is an invention that was obvious to try nevertheless nonobvious?' *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

To differentiate between proper and improper applications of "obvious to try," this court outlined two classes of situations where "obvious to try" is erroneously equated with obviousness under § 103. In the first class of cases, what would have been "obvious to try" would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. *Id.*

In such circumstances, where a defendant merely throws metaphorical darts at a board filled with combinatorial prior art possibilities, courts should not succumb to hindsight claims of obviousness. The inverse of this proposition is succinctly encapsulated by the Supreme Court's statement in *KSR* that where a skilled artisan merely pursues "known options" from a "finite number of identified, predictable solutions," obviousness under § 103 arises. 550 U.S. at 421.

The second class of *O'Farrell's* impermissible "obvious to try" situations occurs where

' what was "obvious to try" was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as

to the particular form of the claimed invention or how to achieve it.
853 F.2d at 903.”

In re Kubin, 561 F.3d 1351, 1359 (Fed. Cir. 2009).

Analysis

Claims 114, 117, 118, 119, and 121

The Combination of References Fails to Disclose or Suggest All the Elements of the Claims

Claim 114 is independent and claims 117, 119, and 121 incorporate all of the elements of claim 114. Claim 114 as amended is directed to a recombinant viral vector having-viral capsid proteins encasing a polynucleotide, wherein one or more of the viral capsid proteins have an organelle localization signal operably linked to a protein transduction domain. None of the cited references either alone or in combination disclose or suggest a recombinant viral vector containing capsid polypeptides modified to contain a protein transduction domain and an organelle localization signal. As a result, the combination of references cannot render the claims obvious and the rejection should be withdrawn.

New Claims

New claim 128 was added specifying that the one or more capsid proteins is gpD. Basis for this amendment is found in the application as originally filed, for example on page 19, lines 17-20. No new matter is introduced.

Allowance of claims 114, 116-119, and 121 is respectfully requested.

Respectfully submitted,

/Charles Vorndran, Ph.D., J.D./
Charles Vorndran, Ph.D., J.D.
Reg. No. 45,315

Date: February 16, 2010

PABST PATENT GROUP LLP
1545 Peachtree Street NE
Suite 320
Atlanta, Georgia 30309
(404) 879-2153
(404) 879-2160 (Facsimile)